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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,997	08/01/2003	Peiyuan Wang	09797.0002-00	8974

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EXAMINER
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HUYNH, CARLIC K

ART UNIT	PAPER NUMBER
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1617

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/12/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/632,997	<b>Applicant(s)</b> WANG ET AL.	
	<b>Examiner</b> Carlic K. Huynh	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20 is/are allowed.
- 6) ☒ Claim(s) 13,14,18,19,21 and 22 is/are rejected.
- 7) ☒ Claim(s) 15-17 and 23-24 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>See Continuation Sheet</u> | 6) <input type="checkbox"/> Other: _____  |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :3 Febrary 2004 and 3 January 2007.

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1-24 are pending in the application, with claims 1-12 having been withdrawn from consideration, in response to the restriction requirement submitted on November 30, 2006. Accordingly, claims 13-24 are being examined on the merits herein.

An amendment to the claims in a Preliminary Amendment to revise claims 1-24, filed on January 16, 2007, is acknowledged.

### ***Election/Restrictions***

2. Applicant's election with traverse of Group XVI, namely claims 13-24, in the reply filed on January 3, 2007 is acknowledged. The traversal is on the ground(s) that the search for the products of Groups [IX-XVI] would uncover the process of use of Groups [I-VIII]. This is not found persuasive because many products can be used with the process of Groups [I-VIII] and thus the search for the products of Groups [IX-XVI] will not necessarily yield the process of Groups [I-VIII]. Furthermore, if the product claims of Groups [IX-XVI] are found allowable, then the process claims of Groups [I-VIII] will be rejoined. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104, as per *In re Ochiai*.

Claims 1-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made with traverse in the reply filed on January 3, 2007.

3. Applicant's election with traverse of the species of a compound of formula (I), namely formula I(J), in the reply filed on January 3, 2007 is acknowledged. The traversal is on the ground(s) that: (1) the searches of the compounds of formula (I) with different bases or sugar-derived substituents should not place an undue burden; and (2) the compounds are found in the same subclass, subclass 221.

Applicants' arguments were not found persuasive. The examiner maintains and argues that there is a search burden for the compounds of formula (I). The different bases or sugar-derived substituents would render each compound of formula (I) to be of a different design and thus a search burden has been established.

Claims 13-24 are read to draw on the elected species of a compound of formula I(J).

The elected species of the compound of formula I(J) was found to be free of the prior art and thus the search was broadened to the compound formula I.

An amendment to the claims in a Preliminary Amendment to revise claims 1-24, filed on January 16, 2007, is acknowledged. Accordingly, claims 13-24 will be examined based on this set of claims.

The restriction requirement and the election of species requirement for a compound of formula (I) are still deemed proper and are therefore made FINAL.

***Information Disclosure Statement***

The Information Disclosure Statement submitted on February 3, 2004 and January 3, 2007 is acknowledged.

***Oath/Declaration***

It does not identify the citizenship of each inventor. Chinese, Belgian, Japanese, Egyptian, Korean, and French are not proper countries of citizenship. Appropriate correction is required.

***Drawings***

The drawings filed on August 1, 2003 have been accepted.

***Specification***

4. The disclosure is objected to because of the following informalities: typographical errors. There are no quotation marks around the term "amino acid" in line 23 on page 44. There are no quotation marks around the term "host" in line 10 on page 45. The quotation marks placed around the term "pharmaceutically acceptable salt or prodrug" should be "pharmaceutically acceptable salt" or "prodrug" in line 21 of page 45.

Appropriate correction is required.

5. The use of the trademark ROFERON®, PEGASYS®, INTRON®, PEG-INTRON®, REBETOL®, and COPEGUS® has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 13-14, 19, and 21 rejected under 35 U.S.C. 102(b) as being anticipated by Sasaki et al. (Journal of Organic Chemistry, 1976, vol. 41, no. 7, pp 1100-1104).

Sasaki et al. teach Compound 4, 9,5'-cyclo-3- $\beta$ -D-ribofuranosyl-8-azaxanthine, which meets the limitations of the instant claims (page 1100 figure).

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited reference. The claims are therefore properly rejected under 35 U.S.C. 102 (b).

7. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Morin et al. (Chemical Research in Toxicology, 1995, vol. 8, pp 792-799).

Morin et al. teach Compound 1, 5'-amino-2',5'-dideoxyguanosine, which meets the limitations of the instant claim (page 794, figure 1).

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited reference. The claims are therefore properly rejected under 35 U.S.C. 102 (b).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sasaki et al. (Journal of Organic Chemistry, 1976, vol. 41, no. 7, pp 1100-1104).

Sasaki et al. teach Compound 4, 9,5'-cyclo-3- $\beta$ -D-ribofuranosyl-8-azaxanthine and that some of the 5-halopyrimidine nucleosides are known to be chemicals of biological interest (page 1100). Furthermore, some of the solvents used to make Compound 4, namely ethanol, are considered pharmaceutically acceptable carriers (page 1103, experimental section for the synthesis of compound 4).

Given that Compound 4 has biological activity and that compounds with biological activity are routinely made into pharmaceutical compositions with pharmaceutically acceptable carriers, it would be obvious to make a pharmaceutical composition of Compound 4 in a pharmaceutically acceptable carrier.

### ***Claim Objections***



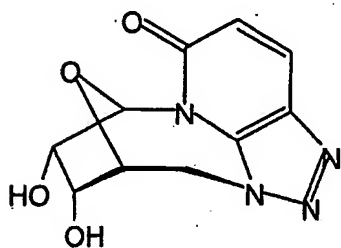
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9. Claims 15-17 and 23-24 are objected to as being dependent upon a rejected base claim, but would be allowed if rewritten in independent form including all of the limitations of the rejected base claim and any intervening claims.

***Allowable Subject Matter***

10. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Claim 20 is directed to a compound of formula:



The following is an examiner's statement of reasons for allowance: claim 20 is free of the prior art. It is the identical structure to the elected species of formula I (J).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance." Claim 20 is allowable because it is free of the prior art.

***Conclusion***

11. No claims are allowed except for claim 20.

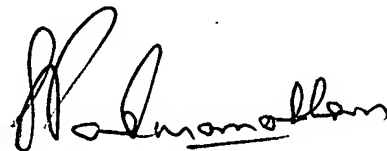
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ckh



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SUPERVISORY PATENT EXAMINER